510(K) SUMMARY K133523

FEB - 6 2014

Submission Correspondent and Owner:	Instratek, Inc. 15200 Middlebrook Dr., Suite G Houston, TX 77058 USA Phone: 281-890-8020 Fax: 281-890-8068 Email: jeff@instratek.com Contact: Mr. Jeff Seavey President
Date summary prepared:	February 4, 2014
Device trade name:	STAPIX™ Superelastic Implant Bone Staples
Device common name:	Bone Staple
Device classification name:	Staple, Fixation, Bone JDR at 21 CFR Part 880.3030
Legally marketed device to which the device is substantially equivalent:	**Memometal Easyclip** Cleared March 19, 2007 under K070031 **Memory Metal Staples, Easyclip** Cleared March 12, 2013 under K122113 **InteliFUSE**, cleared June 29, 2005 under K051408
Description of the device:	The Instratek **STAPIX™** Superelastic Implant Bone Staples kits are comprised of superelastic bone staples in 16 configurations. The Nitinol staples have a finished A(f) temperature of 10°C +/7° to ensure that the material is superelastic at room and body temperatures. The Instratek **STAPIX™** Superelastic Implant is indicated for use in the treatment of bone fractures, osteotomies, and arthrodesis for the reconstructive surgeon. The device is intended for hand and foot surgery. **STAPIX™** bone staples are made from superelastic nickel titanium that does not require cold storage or heating. Implant sizes range from 9mm to 24mm.
Intended use of the device:	The Instratek **STAPIX™** Superelastic Implant is indicated for use in osteotomy and arthrodesis of bones and joints of the hands and feet.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate devices.
Testing:	Performance testing consisted of bending fatigue, static bending, and corrosion.
Conclusions:	The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

Instratek, Incorporated
Mr. Jeff Seavey
President
15200 Middlebrook, Suite G
Houston, Texas 77058

Re: K133523
Trade/Device Name: STAPIX™ Superelastic Implant Bone Staples
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: December 12, 2013
Received: December 13, 2013

Dear Mr. Seavey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K133523

Device Name: STAPIX™ Superelastic Implant Bone Staples

Indications for Use:

The Instratek **STAPIX™** Superelastic Implant is indicated for use in osteotomy and arthrodesis of bones and joints of the hands and feet.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices